

Vinetta Howard-King
Compliance Officer
U.S. Food and Drug Administration
6000 Metro Drive, Suite 101
Baltimore, MD 21228

December 19, 2003

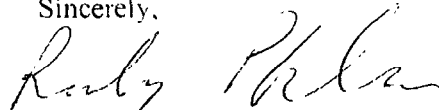
Dear Ms. Howard-King,

Enclosed please find documentation requested in FDA letter dated December 9, 2003.
This documentation includes the following:

1. A copy of each revised standard operating procedure with the initials and dates of the person (myself) who reviewed and approved the new procedure. These initials and dates can be found at the end of each procedure and have been highlighted.
2. A copy of the inservice program training sheet that covers the training of staff involved in autologous blood collection and processing. This training consisted of a review of the FDA inspection findings and the revised procedures.
3. A copy of all revised procedures which involve review/monitoring by the Lab Director which now state the timeframe and where documentation of this review/monitoring by the Lab Director will be done. This addition to the procedures has been highlighted.
4. A copy of the revised procedure for Observation #6 which now includes the length of time used on the [REDACTED] scrub and the length of time to wait for the area to dry. These time frames were obtained from the [REDACTED] product insert. This addition to the procedure has been highlighted.

If you have any questions regarding these items please call me at (434) 315-2610.

Sincerely,



Randy Pfrunder
Lab Director
Southside Community Hospital
800 Oak Street
Farmville, VA 23901
(434) 315-2610
[REDACTED]